DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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WARNING LETTER

NWE-17-03W

VIA FEDEX

May 16, 2003

James Parker, Owner
Vision Group
200 Lafayette Road #5
North Hampton, New Hampshire 03862

Dear Mr. Parker:

On February 13-19 and March 14, 2003, we inspected your facility located at 200 Lafayette Road #5, North Hampton, New Hampshire and collected labeling for your product Precision Vision. Review of your labeling indicates serious violations of the Federal Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Part 101-Food Labeling. You can find the Act along with the food, drug and dietary supplement labeling regulations on the Internet through links on the FDA's web page at www.fda.gov. The following deviations were found.

- The label of the product Precision Vision bears a claim indicating that it is intended to prevent, cure, or mitigate diseases. Such a claim is evidence that the product is intended for use as a drug within the meaning of Section 201(g) of the Act. The following is the claim found on your label:

  "Eye health research has shown evidence of reduced risks and slowed progression of degenerative eye diseases by maintaining high levels of antioxidants and minerals. Those found in this supplement can reduce the risk of age related macular degeneration (the number one cause of blindness in aging persons) and glaucoma."

We also note other claims intended to prevent, cure, or mitigate disease in your promotional literature for Precision Vision.

These claims cause Precision Vision to be a drug as defined in Section 201(g) of the Act. Because this product is not generally recognized as safe and effective when used as labeled, it is also a new drug as defined under Section 201(p) of the Act. Under Section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application.

This product is misbranded under Section 502(a) of the Act because its label is false and misleading in that it suggests that the drug is effective for its intended use in the general population, but the only scientific support for the label claim applies to a limited subset of patients with age-related macular degeneration.

Even if your product did not contain disease claims in its labeling that cause it to be a drug, it would still be misbranded under Section 403(q)(5)(F) of the Act in that the label fails to bear nutrition labeling as required under 21 CFR 101.36. The following are examples:

- Daily values must be declared for vitamin A, beta carotene, vitamin C, selenium, zinc, manganese, and copper as required in 21 CFR 101.36(b)(2)(iii).
- Other dietary ingredients such as bilberry extract, grape seed extract, lutein, bioperine, and taurine that do not have daily values established must be declared using a symbol (e.g., an asterisk) in the column under the heading of "% Daily Value" that refers to the same symbol placed at the bottom of the nutrition label and followed by the statement "Daily Value not established," as required in 21 CFR 101.36(b)(3)(iv).
- The label does not segregate the 21 CFR 101.36(b)(2) and (b)(3) nutrients into separate sections of the supplement facts panel as required by 21 CFR 101.36(b)(3)(i).
- Heavy bars are required immediately after the listing of the last dietary ingredient required to be declared pursuant to 21 CFR 101.36(b)(2) and (b)(3), respectively (21 CFR 101.36(e)(6)(ii) and (iii)).
- The declaration of selenium, copper, manganese, and zinc does not comply with 21 CFR 101.36(d) because the label lists the source ingredient rather than the dietary ingredient as required. The source ingredient that supplies a dietary ingredient may be identified within the nutritional labeling in parenthesis immediately following or indented beneath the name of a dietary ingredient and preceded by the words "as" or "from", e.g., "Copper (as copper chelazome)."
- The label declares 50 mg of selenium amino acid complex. However, this ingredient is a source ingredient of selenium, which is the relevant dietary ingredient for supplement facts labeling purposes. The amount of selenium, not the amount of the source material (i.e., selenium amino acid complex), must be declared in the supplement facts label. 21 CFR 101.36(b)(2)(ii).

- The nutrition labeling ("Supplement Facts") panel does not comply with the format requirements in 21 CFR 101.36(e)(6) in that a heavy bar must be placed beneath the subheading "Serving Per Container" except that if "Serving Per Container" is not required and, as a result, not declared, the bar must be placed beneath the subheading "Serving Size."
- A light bar must be placed beneath the headings "Amount per Serving" and "% Daily Value" as required in 21 CFR 101.36(e)(7).

Other labeling deviations that misbrand your product under section 403 of the Act include the following:

- Failure to list the name and place of business of the manufacturer, packer or distributor on the label. (21 CFR 101.5).
- Failure to list all the ingredients as required by 21 CFR 101.4(a)(1). For example, even though inspection of the product and information from the batch formula indicate that the product contains gelatin, gelatin is not listed as an ingredient.
- Ingredients in the dietary supplements that are not dietary ingredients (i.e., rice flour, magnesium stearate, and gelatin) must be listed outside of the "Supplement Facts" panel as required in 21 CFR 101.4(g).

The above violations are not meant to be an all-inclusive list of deficiencies for your products. It is your responsibility to assure that all products marketed by your firm are in compliance with the Act and its implementing regulations. You should review the labeling for all your products to assure compliance.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement actions without further notice. These actions may include seizure and/or obtaining a court injunction against further marketing of your products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. Copies of revised labeling should be submitted. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Bruce R. Ota, Compliance Officer at the above address.

Gail T. Costello
District Director
New England District